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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,707	04/27/2000	John Greenwood	19141-002	2553

35437 7590 06/06/2003

MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO
666 THIRD AVENUE
NEW YORK, NY 10017

EXAMINER
GUZO, DAVID

ART UNIT	PAPER NUMBER
1636	28

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/559,707	Applicant(s) GREENWOOD ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,24 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *37* is/are allowed.

6)☒ Claim(s) *1, 10 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/973,553* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

The Terminal Disclaimer filed 5/23/03 is acceptable and has been entered.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Tao et al. (U.S. Patent 6,361,771).

This rejection is maintained for reasons of record in the previous Office Action (Papers #15 and 24) and for reasons outlined below.

Applicants traverse this rejection by supplying a Declaration by Dr. Tao under 37 CFR 1.131. Declarant indicates that he developed the modified ARPE-19 cell line and provides evidence that recombinant ARPE-19 cells containing the nucleic acid sequence encoding CNTF were developed prior to the effective filing date of the Tao reference.

The 37 CFR 1.131 Declaration filed on 5/23/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the Tao et al. reference. The instant claims recite ARPE-19 cells containing an expression vector comprising sequences encoding any one of a Markush group of different polypeptides. Tao et al. teaches the same cell

line which can contain an expression vector encoding any one of the same group of polypeptides. Declarant shows, in the Declaration, the reduction to practice of a single embodiment (ARPE-19 cells containing an expression vector encoding the CNTF sequence). This is insufficient to overcome the rejection because

> ...a reference or activity which discloses several species of a claimed genus can be overcome directly under 37 CFR 1.131 only by a showing that the applicant completed, prior to the date of the reference or activity, all of the species shown in the reference. In re Stempel, 241 F.2d 755, 113 USPQ 77 (CCPA 1957). (MPEP 715.02).

Declarant provides no evidence that ARPE-19 cells containing an expression vector encoding IGF I or IGF II or Midkine or IL-6, PEDF, etc. were reduced to practice prior to the effective filing date of the Tao et al. patent. Therefore, the facts set out in the instant declaration would not be sufficient to persuade the skilled artisan that applicant was in possession of so much of the invention as is shown in the Tao et al. reference.

Claim 1 is directed to an invention not patentably distinct from claim 7 of commonly assigned U.S. Patent 6,361,771. Specifically, an ARPE-19 cell line transformed to express one of BDNF, NT-4, Axokine, IGF I or II, Midkine, TNF, NGF, IL-2/3, CNTF, PEDF, LEDGF, etc., which are embodiments of claim 1, is essentially generic to claim 7 of the US Patent 6,361,771 which claims such a cell line with a semipermeable membrane.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,361,771, discussed above, would form the basis for a

rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

This rejection was previously made (see Paper #21) and was erroneously subsequently dropped as a result of applicants' showing (in the response filed 3/14/03) of **current** common ownership of the inventions. The rejection and requirement is reinstated because as noted above, this issue can be overcome by a showing by the assignee that the conflicting inventions **were commonly owned at the time the invention in this application was made**. A showing of current common ownership is not sufficient to obviate this requirement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is noted that the examiner originally rejected claims 10-11 under the Deposit requirement. The cell lines recited in these claims are hRPE-7, hRPE-116 (recited in claim 10) and ARPE-19 (recited in claim 11) and a deposit of all three cell lines is required. Applicants subsequently cancelled claim 11 and applicants have provided written acknowledgement of their duty to deposit the two cell lines recited in claim 10 (hRPE-7 and hREPE-116). However, the ARPE-19 cell line must also be deposited. This rejection is therefore being reapplied to all claims reciting the ARPE-19 as well as the hRPE-7 and hRPE-116 cell lines in order to clarify the record.

Claim 37 is allowed.

This action is made Final because all of the grounds of rejection recited here have been made previously during the prosecution of this application.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be submitted directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
June 5, 2003

DAVID GUZO
PRIMARY EXAMINER